FibroScan®

XL+ Probe

User manual

CE

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1. PURPOSE OF THE USER MANUAL

This User Manual has no contractual value whatsoever and under no circumstances may Echosens be held responsible on the basis of the information contained in this manual.

The present user manual details all of the information required for the implementation, use and maintenance of the probe designed to be connected to the FibroScan. Interpretation of the displayed data is covered in the FibroScan user manual.

Thus, after carefully reading the manual, operators shall be able to:

- connect the probe to the FibroScan,
- use the probe in accordance with technical and clinical requirements,
- carry out the maintenance work of the probe.

Echosens publishes this manual "as is", without guarantees of any nature, whether explicit or implicit, including, but not limited to implicit guarantees or merchant conditions, or adaptation for specific use in view of providing simple and accurate information. Consequently, Echosens cannot accept any responsibility for the manual's incorrect interpretation. Though all efforts have been made to offer a manual that is as accurate as possible, the manual may nevertheless contain some technical inaccuracies and/or typographical errors.

Echosens cannot, under any circumstances, be held responsible for any loss of profit, loss of business, data loss, business interruption, or for any indirect, specific, accidental or consecutive damages of any type. In the event of damages arising from a defect (imperfection) or error contained in this User Manual, Echosens undertakes to send the physician, as rapidly as possible, a hard copy or electronic document containing all corrections made to this manual.

This manual is updated on a regular basis. The most recent version of this manual is available from Echosens on request. Should any major modifications be made to the manual, however, Echosens undertakes to send the physician, as rapidly as possible, a new copy of the manual in hard copy or electronic format. Note that this does not involve updating the hardware and/or software in your possession.

The product owner must keep this manual for as long as the product is used.

This manual contains a chapter for troubleshooting the most commonly encountered problems.

Any information or modification requests pertaining to this manual should be sent to: Echosens, 30 place d'Italie, 75013 PARIS France.

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1.1. SYMBOLS USED IN THE MANUAL

This symbol means: ATTENTION

Warning: see the instructions before using the medical device.

Instructions preceded by this symbol may cause injuries or damage the medical device and installation if not correctly followed.

This symbol means: INFORMATION

Additional information with no impact on instrument use.

1.2. PROPERTY AND COPYRIGHT

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2. WARNINGS

2.1. GENERALITY

Caution: Federal law restricts this device to sale by or on the order of a physician.

2.2. HANDLING THE PROBE

The probe is a fragile electromechanical device that must be handled with care and kept away from liquids. Between two examinations, it should be placed on its holder on the FibroScan. In the event of prolonged non-use, the probe should be stored in its case.

2.3. MAINTENANCE

Maintenance operations must not be performed by a third party other than a technician authorized by Echosens.

The probe must be calibrated periodically. Beyond the period indicated on the calibration certificate, the manufacturer no longer guarantees the performance characteristics of the probe.

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3. MISCELLANEOUS INFORMATION

3.1. GUARANTEE

The terms of guarantee are stated in the Echosens terms of sale documents.

For any request, Echosens remains available to the physician and his/her appointees and shall, if applicable, transfer the request to a competent local representative.

3.2. REGISTERED TRADEMARKS

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4. INDICATIONS AND PRECAUTIONS FOR USE

4.1. INTENDED USE

The FibroScan system with the XL+ probe is an active, non-implantable medical device using ultrasound. This device is designed to be used in a doctor's office.

The FibroScan system with the XL+ probe is intended to provide 50 Hz shear wave speed measurements and estimates of tissue stiffness as well as 3.5 MHz ultrasound coefficient of attenuation parameter (CAP: Controlled Attenuation Parameter) in internal structures of the body.

The FibroScan device is based on the Vibration-Controlled Transient Elastography principle (VCTE^{TM}).

The FibroScan probe comprises a single-element ultrasound transducer mounted on the shaft of the electrodynamic transducer. This transducer generates a transient vibration, which in turn generates an elastic shear wave. This wave propagates through the skin, the subcutaneous tissues, and then the liver. During shear wave propagation, the ultrasound transducer performs a series of ultrasound acquisitions (emission / reception) to measure the speed of shear wave propagation (Vs) in m/s. This measurement corresponds to the spatial and temporal average speed of propagation of the shear wave through the liver region of interest, which can be approximated by a cylinder with a diameter of 1 cm and a length of 4 cm (which corresponds to about 3 cm^3).

In addition, assuming that the liver is a pure elastic, linear and isotropic medium, the device converts shear wave speed Vs into equivalent stiffness E in kPa using the equation $E = 3 \times \rho \times Vs^2$ with ρ the medium density assumed to be 1000 kg/m^3. The values for shear wave speed and equivalent stiffness (or Young's modulus) are relative indexes intended only for the purpose of comparison with other measurements performed using FibroScan devices.

Concomitantly, the ultrasound acquisitions are used to assess the Controlled Attenuation Parameter (CAP). Ultrasound attenuation corresponds to the loss of energy as ultrasound propagates through the medium. Due to attenuation, the intensity of emitted ultrasound (I_0) decreases exponentially with depth (z): $I_z = I_0 \times \exp(-\alpha(f) \times z)$ where I_z is the ultrasound intensity at depth z, α is the frequency (f) dependent attenuation coefficient. Ultrasound attenuation depends principally on (i) the ultrasound frequency, (ii) the properties of the medium of propagation. CAP assesses the value of α at the frequency f = 3.5 MHz and is expressed in dB/m.

Absolute values for these measurements may vary among measurement devices produced from different manufacturers.

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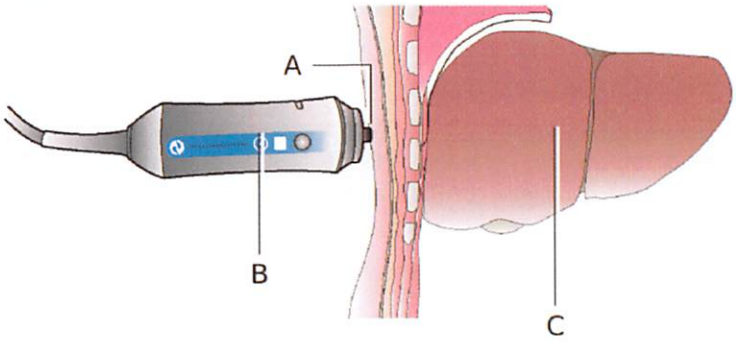
4.2. INDICATIONS FOR USE

FibroScan is indicated for noninvasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as 3.5 MHz ultrasound coefficient of attenuation (CAP: Controlled Attenuation Parameter). The shear wave speed and stiffness, and CAP may be used as an aid to clinical management of adult patients with liver disease. Shear wave speed and stiffness may be used as an aid to clinical management of pediatric patients with liver disease.



How to use a probe: A: *Ultrasound transducer.* ***B:*** *Electrodynamic transducer.* ***C:*** *Liver.*

The values obtained must be interpreted by a physician experienced in dealing with liver disease, taking into account the complete medical record of the patient and the potential presence of different factors known to influence liver shear wave speed or equivalent stiffness and CAP. Based on the existing literature the following, table 1 provides a list of parameters known to increase liver shear wave speed and stiffness.

Table 1: *parameters related to shear wave speed and stiffness.*

Parameter	Reference
Liver fibrosis, cirrhosis	[1-9]
Acute hepatitis, inflammation, ALT flares	[10-13]
Portal pressure, central venous pressure	[14-16]
Extra hepatic cholestasis	[17]
Congestion (heart failure)	[18]
Meal intake	[19]
Amyloidosis	[20-22]

For shear wave speed measurement, the intra and inter-operator agreement has been assessed in a cohort of 200 adult patients with chronic liver disease of various etiologies [23]. The intraclass correlation coefficient was 0.98 both within and between operators. Moreover, in a cohort of 31 NASH children, a 0.96 inter-operator intra class correlation coefficient was found [24]. This demonstrates that intra operator reproducibility is excellent for shear wave speed and stiffness measurements and that changing the operator does not increase measurement variability both in adults and children.

[1] Friedrich-Rust, M., et al., Performance of transient elastography for the staging of liver fibrosis: a meta-analysis. Gastroenterology, 2008. 134(4): p. 960-74.

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[2] Musso, G., et al., Meta-analysis: Natural history of non-alcoholic fatty liver disease (NAFLD) and diagnostic accuracy of non-invasive tests for liver disease severity. Annals of Medicine, 2011. 43(8): p. 617-49.

[3] Shaheen, et al., FibroTest and FibroScan for the Prediction of Hepatitis C-Related Fibrosis: A Systematic Review of Diagnostic Test Accuracy. American Journal of Gastroenterology, 2007: p. 1-12.

[4] Shi, K.Q., et al., Transient elastography: a meta-analysis of diagnostic accuracy in evaluation of portal hypertension in chronic liver disease. Liver Int, 2013. 33(1): p. 62-71.

[5] Smith, J.O. and R.K. Sterling, Systematic review: Non-invasive methods of fibrosis analysis in chronic hepatitis C. Alimentary Pharmacology and Therapeutics, 2009. 30(6): p. 557-76. [6] Stebbing, J., et al., A Meta-analysis of Transient Elastography for the Detection of Hepatic Fibrosis. Journal of Clinical Gastroenterology, 2010. 44(3): p. 214-9.

[7] Talwalkar, J.A., et al., Ultrasound-based transient elastography for the detection of hepatic fibrosis: systematic review and meta-analysis. Clinical Gastroenterology and Hepatology 2007. 5(10): p. 1214-20.

[8] Tsochatzis, E.A., et al., Elastography for the diagnosis of severity of fibrosis in chronic liver disease: A meta-analysis of diagnostic accuracy. Journal of Hepatology, 2011. 54(4): p. 650-9.

[9] Lee, C.K., et al., Serum Biomarkers and Transient Elastography as Predictors of Advanced Liver Fibrosis in a United States Cohort: The Boston Children's Hospital Experience. The Journal of pediatrics, 2013. 163(4): p. 1058-64.

[10] Arena, U., et al., Acute viral hepatitis increases liver stiffness values measured by transient elastography. Hepatology, 2008. 47(2): p. 380-4.

[11] Coco, B., et al., Transient elastography: a new surrogate marker of liver fibrosis influenced by major changes of transaminases. Journal of Viral Hepatitis, 2007. 14(5): p. 360-9.

[12] Mueller, S., et al., Increased liver stiffness in alcoholic liver disease: differentiating fibrosis from steatohepatitis. World Journal of Gastroenterology, 2010. 16(8): p. 966-72.

[13] Sagir, A., et al., Transient elastography is unreliable for detection of cirrhosis in patients with acute liver damage. Hepatology, 2008. 47(2): p. 592-5.

[14] Carrión, J.A., et al., Transient elastography for diagnosis of advanced fibrosis and portal hypertension in patients with hepatitis C recurrence after liver transplantation. Liver Transplantation, 2006. 12(12): p. 1791-8.

[15] Millonig, G., et al., Liver stiffness is directly influenced by central venous pressure. Journal of Hepatology, 2010. 52(2): p. 206-10.

[16] Vizzutti, F., et al., Liver stiffness measurement predicts severe portal hypertension in patients with HCV-related cirrhosis. Hepatology, 2007. 45(5): p. 1290-7.

[17] Millonig, G., et al., Extrahepatic cholestasis increases liver stiffness (FibroScan) irrespective of fibrosis. Hepatology, 2008. 28(5).

[18] Lebray, P., et al., Liver stiffness is an unreliable marker of liver fibrosis in patients with cardiac insufficiency. Hepatology, 2008. 48(6): p. 2089.

[19] Mederacke, I., et al., Food intake increases liver stiffness in patients with chronic or resolved hepatitis C virus infection. Liver International, 2009. 29(10): p. 1500-6.

[20] Janssens, E., et al., Hepatic amyloidosis increases liver stiffness measured by transient elastography. Acta Gastroenterologica Belgica, 2010. 73(1): p. 52-4.

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[21] Lanzi, A., et al., Liver AL amyloidosis as a possible cause of high liver stiffness values. European Journal of Gastroenterology and Hepatology, 2010. 22(7): p. 895-7.

[22] Loustaud-Ratti, V.R., et al., Non-invasive detection of hepatic amyloidosis: FibroScan, a new tool. Amyloid, 2011. 18(1): p. 19-24.

[23] Fraquelli, M., et al., Reproducibility of transient elastography in the evaluation of liver fibrosis in patients with chronic liver disease. Gut, 2007. 56(7): p. 968-73.

[24] Nobili, V., et al., Accuracy and reproducibility of transient elastography for the diagnosis of fibrosis in pediatric nonalcoholic steatohepatitis. Hepatology, 2008. 48(2): p. 442-8.

4.3. PROBE AND EXAMINATION SELECTION CRITERIA

The recommendations for using the probes are defined by the following patient's morphological data:

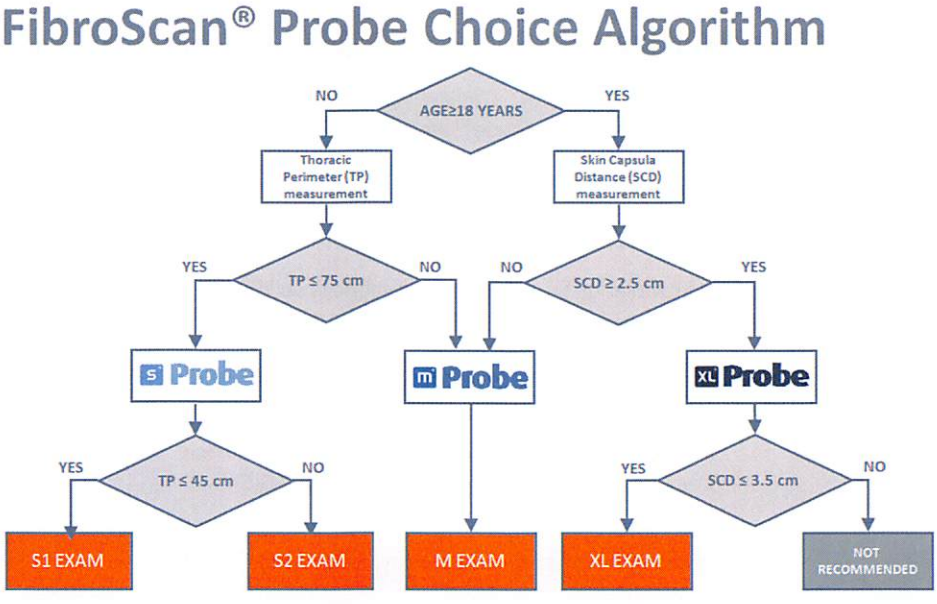
- TP: Thoracic Perimeter measured at the xiphoid using a tape measure.
- SCD: Skin-to-Capsule Distance assessed with an ultrasound scanner or by the automatic probe selection tool.

In case of using an ultrasound scanner, SCD should be measured at the point where the shear wave speed is measured with a pressure similar to the one used with the FibroScan probe.

In case of using the automatic probe selection tool, please refer to FibroScan 502 Touch User manual (chapter 6.5.11. Exam type selection area).

It is not recommended to use any means to compress the soft tissues merely to reduce the SCD.

Four types of examination are available: S1, S2, M and XL. They correspond to specific measurement depths that take into account the liver's depth beneath the skin.



In all cases, Echosens recommends to perform 10 valid FibroScan measurements.

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4.4. PRECAUTIONS FOR USE

The following instructions must be followed in order to ensure patient safety. Thus, the present probe designed for the FibroScan should not be used in the following situations:

- On patients under 18 years old.
- On patients with skin-to-capsule distance (SCD) less than 25 mm or greater than 35 mm.
- On an organ other than the liver. The eyes and mucosa must absolutely be avoided.
- On patients with active implants such as pacemakers, defibrillators, pumps, etc.
- On wounds.
- On pregnant women.

Moreover, presence of ascites between the probe and the liver may prevent from obtaining measurement with the device.

The clinical personnel must follow normal safety procedures.

The FibroScan examination should be performed prudently using the principle of ALARA (As Low As Reasonably Achievable).

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4.5. USER TRAINING

Only persons who have received training in the use of the FibroScan unit and who possess a user certificate are authorized to conduct an examination using FibroScan. Training is essential for correct equipment use and in order to obtain reliable and reproducible measurements.

This manual is not intended to provide user training.

4.6. ELECTRICAL SAFETY

The probe, designed for the FibroScan, has been manufactured and tested in accordance with IEC electromagnetic compatibility (EMC) and electrical safety standards. It leaves the factory in full compliance with safety and performance requirements. In order to maintain this compliance and to guarantee the safe use of the medical device, the user must conform to the indications and symbols contained in this manual.

Safe use is no longer guaranteed in the following main, non-exclusive cases:

- the probe is visibly damaged,
- the probe does not work,
- after prolonged storage in unfavorable conditions,
- after serious damage incurred during transport.

When safe use of the probe is no longer possible, the probe must be taken out of service. Steps must be taken to avoid its inadvertent use. The probe should be handed to authorized technicians for inspection.

4.7. MAINTENANCE-RELATED SAFETY

For all maintenance operations, the physician and his/her appointees should contact Echosens, who will send an authorized technician.

For correct and safe use and for all maintenance operations, the personnel must conform to normal safety procedures.

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5. EXTERNAL PRESENTATION

5.1. HARDWARE SUPPLIED

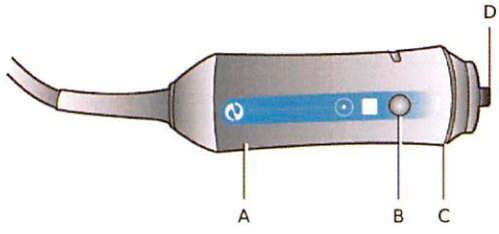
When opening the package, ensure the contents match the following list:

- Probe and case
- User Manual

5.2. PROBE DESCRIPTION

Housing

The housing contains an electrodynamic transducer (vibrator), an ultrasound transducer and a measurement trigger button.



***Probe housing: A:** Electrodynamic transducer. **B:** Measurement button. **C:** Indicator light (LED). **D:** Ultrasonic transducer.*

The ultrasound transducer of the probe is a "Type B" applied part, and is the only component of the FibroScan unit in contact with the patient.

Measurement button

As soon as this button is pressed (if sufficient pressure is exerted on the transducer), the vibrator actuates the electrodynamic transducer, which in turn generates a shear wave (s-wave) that painlessly impacts the patient's skin. The ultrasound transducer performs a series of acquisitions (emission / reception) to measure the propagation speed of this shear wave. Acquisition lasts less than one tenth of a second.

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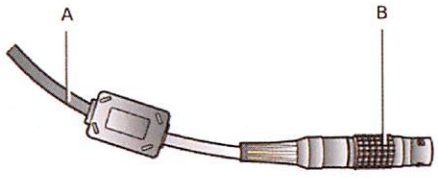
Indicators

The indicator lights (LEDs) display a status as follows:

- On during FibroScan start-up and when standing by to launch an exam.
- Flashing lights for the probe selected when an exam starts.
- Switched off during an exam when the operator is applying an incorrect pressure to the patient's body.
- On during an exam when the operator is applying the correct pressure to the patient's body. It is however strongly recommended that you view the pressure exerted by looking at the on-screen pressure indicator.

Lead



Probe lead: A: *Connection cable.* ***B:*** *Connection jack.*

This 1.5 m lead connects the probe to the FibroScan by means of a multi-pin jack.

The probe transducer, the probe jack, and the FibroScan connector are fragile elements and must be handled with care.

The probe jack has a red dot that should be aligned with the red dot on the FibroScan socket before insertion.

The serial number marked on the connector identifies the probe uniquely.

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6. USE DURING AN EXAMINATION

6.1. USER RECOMMANDATIONS

The following recommendations must be followed during the different phases of an examination.

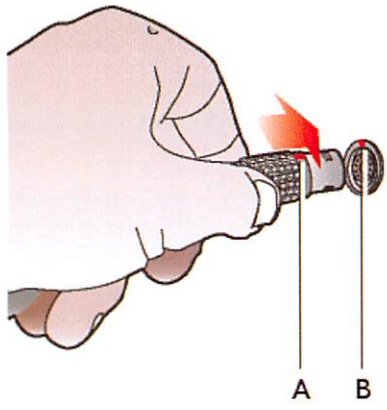
- Hold the probe perpendicular to the patient's skin during the measurements.
- Avoid probe impacts.
- Do not immerse the probe.
- Avoid any liquid projections on the medical device.
- Clean and decontaminate the probe with a suitable product (see paragraph Cleaning, maintenance and repairs).
- Place the probe after use in one of the holders or in its case.

6.2. CONNECTING / DISCONNECTING THE PROBE

- Location of the probe connector: user manual.
- To insert the probe jack: align the probe lead jack's red dot with the socket's red dot and insert the jack.

Both the jack and socket are fragile elements. Handle with care.

To connect the probe lead, insert the jack after aligning the red dots.



Connecting the probe: A: *Red dot on probe socket.* ***B:*** *Red dot on probe jack.*

- To disconnect the probe jack: first pull the jack's splined sleeve back to unlock it, then pull the whole jack back.

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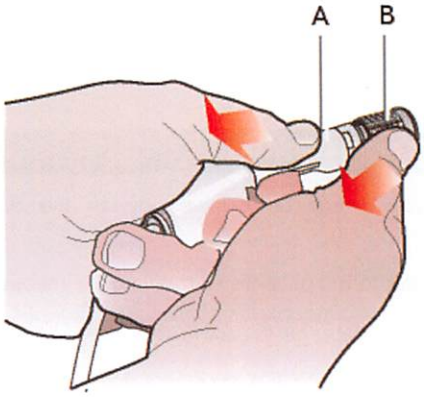
When starting an exam, be sure to follow the instruction in this message: "Do not unplug the probe until the end of the exam."

A probe may be disconnected for replacement with another probe between two examinations. If the probe is disconnected during an examination, this examination is automatically closed.



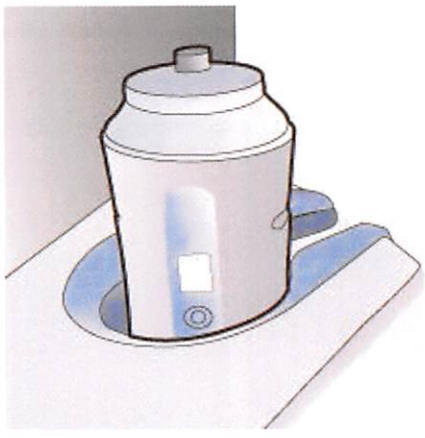
***Disconnecting the probe: A:** Socket. **B:** Splined sleeve.*

6.3. HANDLING THE PROBE

Refer to the warnings in Chapter 2 concerning the handling of the probe.

6.3.1. Probe resting position

When the probe is not in use, it must be positioned on the probe holder, as shown.



Probe resting position.

6.3.2. Gripping the probe

Hold the probe as shown. During measurements, continuously make sure that the probe is maintained perpendicular to the skin surface of the patient.

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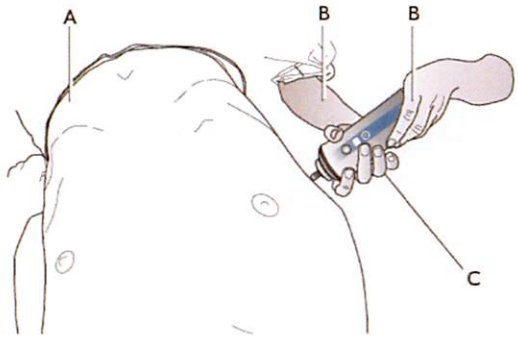

***Gripping the probe: A:** Patient. **B:** Operator. **C:** Probe.*

6.4. END OF EXAMINATION

Once the examination is complete, proceed as follows:

1. Click on the button below to deactivate the probe.
2. Remove any excess gel in holding the probe, head pointing downwards.
3. Disinfect the probe with a suitable product indicated in paragraph Cleaning, maintenance and repairs.
4. Place the probe, head pointing up, onto the FibroScan probe holder.
5. If the device is no longer required:
   - Press the on/off button next to the monitor of the FibroScan.
   - Set the main switch to the 0 position.
   - Disconnect the probe as indicated in paragraph Connecting / disconnecting the probe.
   - Store the probe in its case.

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7. CLEANING, MAINTENANCE AND REPAIRS

In the event of malfunction, only the staff of Echosens or its local representative are authorized to service FibroScan and its accessories. Any work performed by an unqualified person will terminate the guarantee.

7.1. CLEANING

Apply the following recommendations to clean or disinfect the probe.

Failure to observe these recommendations may result in damage to the probe, which will then no longer be covered by the guarantee.

Recommendations

- Always wear eye protection and gloves to prevent injury.
- Observe the expiry dates of cleaning products and decontamination solutions.
- Ensure that the contact time and concentration of the cleaning product and decontamination solution are appropriate for the equipment used. Carefully apply the instructions given on the label of the cleaning product and the decontamination solution.
- Carefully read the recommendations from the Association for Professionals in Infection Control and Epidemiology (APIC) and the Food and Drug Administration (FDA), if applicable in the country.

7.1.1. Cleaning the probe (housing, cable and transducer)

It is not necessary to switch off the device before cleaning the probe.

Surfaces must be cleaned in strict compliance with the following procedure:

1. Gently remove the gel using a soft cloth or wipe.

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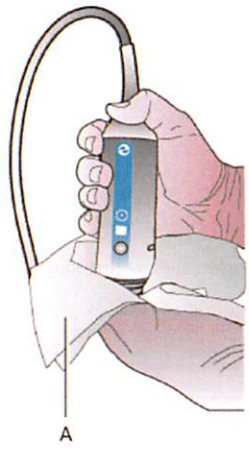

Cleaning the probe: A: *Wipe.*

2. Remove all traces of bodily fluid by cleaning the surfaces using a soft cloth or wipe soaked in the recommended cleaning product.
3. If necessary, rinse the cleaned surfaces using a soft cloth soaked in water.
4. Dry, if necessary, using a dry cloth.
5. Wipe the surfaces using a soft cloth or wipe soaked in the recommended decontamination solution.
6. Dry, if necessary, using a soft dry cloth.
7. Examine the transducer and probe cable for any damage such as cracks, breakage, or liquid leakage.

If any damage is observed, stop using the probe and contact Echosens or its local representative: service@echosens.com.

Precautions

Do not submerge or soak the probe.

Apply the cleaning product and decontamination solution to the soft cloth, not directly on the surface to be cleaned.

The probe must be cleaned after every use or between patients. Prior cleaning is necessary in order to ensure effective decontamination.

Do not use a surgeon's brush to clean the probe. Even the use of flexible brushes could damage the probe.

Take care not to introduce any cleaning product or decontamination solution into the probe connector.

7.1.2. Recommended cleaning products

Echosens recommends use of the following products:

- Pure water, soapy water.
- Detergent with neutral pH (5 to 8).
- Recommended decontamination solutions (see below).

The following cleaning products are **prohibited**:

- Abrasive products (such as "Cif" and scouring powders)
- Alkaline detergents (pH > 9), bleach, etc.

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- Sulphuric, acetic, nitric, hydrochloric, and oxalic acid, etc.
- Soda, potash, ammonia, etc.
- Unleaded petrol, acetone, MED, MBK, toluene, xylene, benzene, trichloroethylene, etc.
- Nail varnish solvent and remover.

7.1.3. Recommended decontamination solutions

The decontamination solutions recommended below are suitable for use on the machine and probes.

Cleaning and decontamination solution	**Origin**	**Type**	**Active ingredient**
105 Spray	USA	Vaporizer	Quaternary ammonium
Ascend	USA	Liquid	Quaternary ammonium
Control III	USA	Liquid	Quaternary ammonium
Coverage Spray	USA	Vaporizer	Quaternary ammonium
End-Bac II	USA	Liquid	Quaternary ammonium
PI-Spray	USA	Vaporizer	Quaternary ammonium
PI-Spray II	USA	Vaporizer	Quaternary ammonium
Thericide Plus	USA	Liquid	Quaternary ammonium
Thericide Plus	USA	Vaporizer	Quaternary ammonium
Clinell Wipes	United Kingdom	Wipes	Quaternary ammonium
Tristel Wipes System	United Kingdom	Wipes	Chlorine dioxide
Tuffie	United Kingdom	Wipes	Quaternary ammonium
Surfanios Premium	France	Liquid	Quaternary ammonium
Aniosurf Premium	France	Liquid	Quaternary ammonium
Wip'Anios	France	Wipes	Quaternary ammonium
Wip'Anios Premium	France	Wipes	Quaternary ammonium
Surfa'Safe SH	France	Vaporizer	Quaternary ammonium
Viraclean	France	Vaporizer	Quaternary ammonium

In addition to the list of recommended decontamination solutions, any alcohol-free decontamination solutions using quaternary ammonium as an active agent can be used to decontaminate the probes.

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7.2. CALIBRATING THE PROBE

The probe contains mechanical parts that may shift slightly over time.

The probe must therefore be periodically calibrated. Beyond this period, the manufacturer no longer guarantees the performance characteristics of the probe.

As soon as the deadline is reached, an icon is displayed in the information window during the examination.

The user then has one month to send the probe to Echosens for calibration.

Despite the presence of the icon, the operator can perform examinations as usual. We strongly recommend, however, sending the probe for calibration as rapidly as possible.

Calibration icon.

7.3. TROUBLESHOOTING

Events	Solutions
The probe is no longer calibrated.	Contact Echosens or its local representative: service@echosens.com.
"Hardware error" message.	Check that the probe is correctly connected.
"Vibration error" message.	Incorrect transducer movement.

In the event of a failure or malfunction, please contact Echosens or its local representative: service@echosens.com.

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8. TECHNICAL CHARACTERISTICS

Manufacturer	Echosens 30 place d'Italie 75013 PARIS – France
Model	Type XL+
IP Code	IPX1: the probe, excluding connectors, is protected from vertically falling drops of water.
Mechanical Index	MI < 1.0 for all operation mode.

8.1. ULTRASOUND TRANSDUCER

Central frequency	2.5 MHz
Measurement depth	35 mm to 75 mm

Acoustic output

The acoustical outputs are maximal during the transient elastography sequence which is a mixed between M mode and Elastography acquisition mode.

Acoustic Output			**MI**	**$I_{SPTA.3}$ (mW/cm^2)**	**$I_{SPPA.3}$ (W/cm^2)**
Pre-amendments					
Global Maximum Value (95 % T.L. for 99 % of measurements values)			0.44	4.8	11.9
Associated acoustic parameter Maximum values	$p_{r.3}$ (MPa)		0.56 (± 7 %)		
	W_o (mW)			2.1 (± 22 %)	2.1 (± 22 %)
	f_c (MHz)		2.35 (± 3 %)	2.35 (± 3 %)	2.35 (± 3 %)
	z_{sp} (cm)		3.75 (± 5 %)	3.75 (± 5 %)	3.75 (± 5 %)
	Beam dimensions	x_{-6} (cm)		0.7 (± 6 %)	0.7 (± 6 %)
		y_{-6} (cm)		0.74 (± 6 %)	0.74 (± 6 %)
	PD (µsec)		0.791		0.791
	PRF (Hz)		500		500
	EBD	Az. (cm)		1.12 (± 6 %)	
		Ele. (cm)		1.11 (± 6 %)	
Operating control conditions	Control 1	NPL ultrasound beam calibrator	NPL ultrasound beam calibrator	NPL ultrasound beam calibrator	

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8.2. ELECTRICAL CHARACTERISTICS

EMI	See the FibroScan user manual.

8.3. MECHANICAL CHARACTERISTICS

Dimensions	158 mm x 52 mm (L x diameter)
Weight	500 grams

8.4. ENVIRONMENTAL PROPERTIES

Operating temperature	+ 10 °C to + 40 °C (+ 50 °F to + 104 °F)
Operating humidity	30 % to 75 % relative humidity, non-condensed
Storage temperature	– 20 °C to + 70 °C (– 4 °F to + 158 °F)
Storage humidity	10 % to 85 % relative humidity, non-condensed

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